DEPARTMENT OF VETERANS AFFAIRS
South Texas Veterans Health Care System
San Antonio, Texas 78229-4404

Research Service Policy Memorandum 11-40

March 2, 2011

RESEARCH STANDARD OPERATING PROCEDURES (SOP)
External Clinical Research Monitoring Visits

1. **PURPOSE:** To describe the policies and procedures for the Research and Development (R&D) Office and STVHCS Investigators with respect to monitoring by external agencies [i.e., pharmaceutical companies, study sponsors, Contract Research Organizations (CROs), VA Cooperative Studies Program (CSP) Monitors] for clinical research approved at the STVHCS.

2. POLICY: Investigator records (i.e., regulatory documents, case report forms, correspondence, study files) and subject's medical records [i.e., source documents, Computerized Patient Records System (CPRS), informed consent documents] are subject to inspection and monitoring by external agencies [i.e., pharmaceutical companies, study sponsors, Contract Research Organizations (CROs), VA Cooperative Studies Program (CSP) Monitors]. These site visits may be routine or conducted for specific causes. In accordance with the facilities Human Subjects Protection Program (HRPP), any findings or issues of concern resulting from a monitoring visit must be forwarded to the STVHCS R&D Office to assess if they are appropriately addressed and to assure the appropriate facility officials and committees are notified.

3. ACTIONS:

a. Upon Notice of a monitoring visit

The R&D office is to be notified of all monitoring visits by external monitoring agencies as soon as possible. This is the responsibility of the research staff person who schedules or confirms the monitoring visit. Notification should be by email to KimberlyK.Summers@va.gov. If the monitoring visit is unscheduled, the Deputy ACOS for Research is to be notified as soon as the study personnel are aware of the visit. This may be done by telephone at 210-617-5123.

b. At the time of the monitoring visit

(1) The CRO or study monitor must sign in at the R&D Office as a visitor and receive a Research Monitor Visitor badge. A Research Monitor Log will be maintained by the R&D Office using VA form 4793 or modified form, which will collect the following information: NAME, DESTINATION ROOM OR LAB #, DATE, TIME IN, TIME OUT, DOSIMETER NEEDED Y/N, REMARKS/BADGE #

(2) Visitor badges will be issued after copying a picture ID. The Research Monitor Visitor badge must be worn at all times. Badges must be returned to the Research office by 4:30pm.

(a) Monitors conducting business past 4:30pm should return their visitor badge to the responsible investigator or study staff who must ensure the badge is returned the next business day.

(b) Lost or stolen badges will be assessed a $25 fee to the responsible investigator. Lost or stolen badges will be reported to the STVHCS Police Service immediately.

(c) Monitors assigned a Research Monitor Visitor badge must be accompanied by a VA employee (paid or WOC) at all times.

(d) The research office will maintain accountability of all issued badges and visitor sign in sheets. When requested, these records will be made available to Police Service for auditing purposes.

(e) Lost or stolen badges will be reported to Police Service immediately at which time color coding of the research monitor visitor badge will be changed.

(3) The PI or designated study staff must inform the monitor that any potential or actual serious findings must be conveyed to the investigator and the research office during an exit interview. Findings that require an exit interview include but are not limited to:

(a) Any suspicions or concerns that serious non-compliance may exist

(b) All findings of serious non-compliance with study protocol, Institutional Review Board (IRB) requirements or applicable regulations and policies (i.e., failure to consent subjects, entering subjects who do not meet entrance criteria into protocols, failure to report serious or unexpected adverse events).

(c) Monitoring visits conducted by a regulatory agency (FDA, OHRP)

(4) The CRO or study monitor must provide a signed External Monitor Agreement form (attachment 1) to the R&D office prior to initiation of the site visit.

(a) During the monitoring activities, the external monitor may only access information and research data that is necessary and in accordance with the approved protocol.

(b) The external monitor may not review data in the electronic medical record except under the direct supervision of the STVHCS research staff.

(5) The CRO or study monitor will complete and sign the "STVHCS Report of Clinical Research Monitoring Visit" form (attachment 2). Completion of this form is required independent of the findings associated with the visit.

c. **Following the monitoring visit**

(1) The PI or designated study staff must forward all completed "STVHCS Report of Clinical Research Monitoring Visit" forms to the R&D Office.

(2) All monitoring reports with potential or actual serious findings will be evaluated in accordance with the STVHCS UPIRSO and Noncompliance Policies to implement the appropriate reporting mechanisms. Summary reports of monitoring visits will be reported to the R&D committee for review and recommendations at least annually.

(3) All monitoring reports with potential or actual serious findings will be forwarded to the next R&D Committee meeting for review and recommendations.

4. **REFERENCES**: DVA Memorandum "Reporting of All Study Site-Monitoring Visit Results" dated Oct 14 2004 from the Acting Deputy Under Secretary for Health; Research Service Human Subjects Concerns Complaints Allegations of Research Improprieties Standard Operating Procedure No. 26

5. **RESPONSIBILITY:** ACOS for Research and Development (151)

6. **RESCISSION:** Research Service Policy Memorandum 08-40, dated February 29, 2008

7. **RECERTIFICATION:** March 2016

Kimberly K Summers, PharmD

KIMBERLY K. SUMMERS, PHARM.D.
Acting ACOS for Research and Development

ATTACHMENTS (2)

DEPARTMENT OF VETERANS AFFAIRS
South Texas Veterans Health Care System
7400 Merton Minter Blvd
San Antonio, Texas 78229

STVHCS External Monitor Agreement Form

All external monitors reporting to the STVHCS must follow all relevant policies and procedures while visiting.

This External Monitor Agreement Form must be signed and returned to the STVHCS R&D Office prior to initiation of monitoring visit.

All external monitors must sign in as a visitor at the R&D Office and receive a visitor's badge.

External monitors may only access research data and protected health information that is necessary and in accordance with the approved protocol.

External monitors are not allowed unsupervised access to the electronic medical record (CPRS) or to any other nonresearch records that contain identifiable protected health information (PHI).

Research data located within CPRS may only be viewed under the direct supervision of the STVHCS research staff in a "chauffer" manner (research staff must log in and navigate through the computerized record for the monitor to view the necessary research information).

Any potential or actual serious finding must be conveyed to the investigator and the research office during an exit interview at the time of the monitoring visit.

External monitors must complete the "STVHCS Report of Clinical Research Monitoring Visit" form prior to departure from the facility.

A written follow up report is required for any potential or actual serious findings and must be forwarded to the principal investigator and the STVHCS R&D Office.

Signature of Monitor: _____

Printed Name of Monitor and company represented: _____

Responsible Principal Investigator: _____

DEPARTMENT OF VETERANS AFFAIRS
South Texas Veterans Health Care System
7400 Merton Minter Blvd
San Antonio, Texas 78229

STVHCS Report of Clinical Research Monitoring Visit

Date: _____

Principal Investigator: _____

Study Name: _____ IRB #_____

Was this visit-pre arranged? ___NO ___YES

Auditor(s): _____ Company: _____

_____ **Indicate relationship to research:**

_____

- ☐ Sponsor
- ☐ Clinical Research Organization
- ☐ VA CSP Monitor
- ☐ Regulatory Agency

Reason for visit:

- ☐ Initiation Visit
- ☐ Routine / Periodic Monitoring Visit
- ☐ For Cause Visit
- ☐ Close-Out Visit

Check all that apply:

☐ Results of this monitoring visit are satisfactory; no concerns of serious non-compliance
Complete form and return to R&D Office with visitors' badge

☐ Results of this monitoring visit found suspicions or concerns of serious non-compliance
Highlight your findings below and contact the VA R&D Office to schedule an exit interview at 210-617-5123

☐ This was a Regulatory Agency Visit (FDA, OHRP)
Contact the VA R&D Office to schedule an exit interview at 210-617-5123

If applicable, findings associated with suspicions or concerns of serious non-compliance*:

_____

_____

*If suspensions or concerns of serious non-compliance are identified a follow up report must be carbon copied to the STVHCS R&D Office.

Signature of Monitor: _____

Printed Name of Monitor: _____

Do you have an anticipated date of next visit? ___NO ___YES, **if yes** date _____

Attachment 2